K082944

OCT 1 6 2008

Section 15

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CRF 807.92.

1. Submitter's name, address, telephone number, contact person, and date summary prepared

a. Bausch & Lomb Incorporated
1400 N. Goodman Street
Rochester, N.Y. 14609
(585) 338-8467

b. Contact Person: David U, Thomas, M.S., R.A.C.
Manager, Global Regulatory Affairs

c. Date Summary Prepared: September 4, 2008.

2. Name of device, including trade name and classification name:

a. Trade/Proprietary Name: Crystalsert™ Crystalens® Delivery System

b. Classification Name: Intraocular lens guide

3. Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

Company:	Chiron Vision Corporation (currently acquired by Bausch & Lomb Corporation
Device:	MPort (MP-30)
510(k)	K970727
Date Cleared:	December 17, 1997

4. A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant

physical and performance characteristics (design, material, physical properties):

The Crystalsert consists of a plunger, body, drawer and inserter tip. All of the components are manufactured with medical grade polypropylene. There is also a stainless steel spring for the plunger return. The plunger tip is 2.8 mm that requires the lens to be folded when delivered. The body has a loading dock area for placement of the lens with forceps with an additional notch to allow for correct haptic placement. Once the lens is placed in the loading dock, the drawer is pressed closed and then the plunger can be depressed to deliver the lens. Finger flanges are also built onto the body to assist in the deliver.

5. Statement of intended use:

The Crystalsert™ Crystalens delivery system is intended to be used to fold and deliver the Crystalens® (AT-50SE and AT-52SE) accommodating intraocular lens into the capsular bag.

6. Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.

Technical Comparison Matrix

MPort (MP-30)	Crystalsert Inserter
Operating Principle	
• Lens is loaded into inserter through loading deck and then pushed into position by closing drawer. Lens is laying flat in loading deck when drawer is closed. Haptic puller is used to place leading haptic in correct loading position. • Lens is delivered by direct forward motion of syringe-type plunger • Single lens is inserted through a 3 mm inserter tip. Lens is folded when pushed through tip.	• Lens is loaded into loading dock in unfolded flat state. Lens is put in proper position for loading by closing drawer. No haptic puller is necessary. • same • Single lens is inserted through 2.8 mm inserter tip. Lens is folded when pushed through tip.
Design	
The inserter consists of plunger, inserter body, drawer and haptic puller.	The inserter consists of plunger, inserter body, and drawer. A loading

A loading dock is attached to the end of the inserter body.	dock is attached to end of inserter body. Additional notch is cut in loading area to allow for correct haptic placement.
Material	
The inserter is single use and consists of Medical Grade Polypropylene with PA-208 lubricant. The plunger return spring is stainless steel and the plunger O-ring consists of silicone.	The body and drawer consist Medical Grade Polypropylene material ((Huntsman) with 1% by weight InCon GMB#2 Lubricant) and the Plunger is medical grade polypropylene from BP Amoco. Plunger return spring is stainless steel. No plunger O-ring is used with this plunger.
Labeling	
Indications for Use: The Mport Foldable Lens Placement system is indicated for compressing and inserting a Soflex™ series multi-piece intraocular lens into the eye during small incision cataract surgery.	Indications for Use: The Crystalsert™ Crystalens delivery system is intended to be used to fold and deliver the Crystalens® (AT-50SE, AT-52SE, HD520 and HD500) accommodating intraocular lens into the capsular bag.
Cleaning/Sterilization Information	
Product is EtO sterilized to a SAL of 10^{-6}. No cleaning is necessary or recommended. Product is Single-Use only. The inseter will be labeled with a 6 month shelf life.	same
Validations	
Validated for use with LI61U, LI51U, C31UB and Silens6/Soflex 2. Bausch & Lomb Ocucoat Viscoelastic and Amvisc viscoelastics can used.	Validated with Crystalens models AT-50SE or AT-52SE and validated with Bausch & Lomb Viscoelastic Amvisc Plus.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2008

Bausch & Lomb, Inc.
c/o Jay Y. Kogoma
Intertek Testing Services
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K082944
Trade/Device Name: Cystalsert™ Crystalens® Delivery System
Regulation Number: 21 CFR 886.4300
Regulation Name: IOL Inserter/Injector
Regulatory Class: I
Product Code: MSS
Dated: October 1, 2008
Received: October 2, 2008

Dear Mr. Kogoma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082944

Device Name: Crystalsert™ Crystalens® Delivery System

Indications For Use:

The Crystalsert™ Crystalens® Delivery System is intended to be used to fold and deliver the Crystalens® (AT-50SE, AT-52SE, HD520 and HD500) accommodating intraocular lens into the capsular bag.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kesia Alexander

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K082944